



## REPRESENTATIVE CHUCK BENEDICT

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The Public Testimony of Representative Chuck Benedict on SB 71  
Senate Committee on Health and Human Services  
September 5, 2007

Chairman Erpenbach and Honorable Members of the Senate Committee on Health and Human Services,

Thank you for allowing me the opportunity to share my comments with you today. Please accept this letter as my endorsement of Senate Bill 71, legislation that will prohibit substitution of brand name anti-seizure medications with generic equivalents without the approval of the patient and prescribing physician.

This proposal is important because some patients require very specific blood levels and have very narrow therapeutic ranges. This can require the specificity of dose that may only be available from a specific name brand. Generics are +/- 7% bio-equivalent and there are formulation differences from one manufacturer to another.

Unlike other classes of medications, anticonvulsant medications for the treatment of epilepsy differ in several ways that make generic substitution problematic. Small variations in concentrations of active ingredients can be life threatening and/or cause seizures when taken by those with epilepsy.

In addition, different generics may vary in the inert packing material that compose a portion of the pill, which may dissolve differently than the brand name pill, or otherwise have different and inconsistent pharmacokinetics. This could lead to toxicity in the case of too rapid absorption, or sub-therapeutic blood levels and breakthrough seizures should the absorption be too slow.

A single breakthrough seizure not only puts a person at great physical risk, it places them in financial jeopardy as well. In Wisconsin, as in many states, a person who experiences a seizure automatically loses his or her license until they can demonstrate that they have been seizure-free for 90 days. This is disruptive to employment, family, and the general responsibilities of life.

I strongly support Senate Bill 71 because it would require informed consent of physicians and patients before generic substitutions of anticonvulsants are made.

Please do not hesitate to contact me should you have any questions. I thank you for your time and consideration.

Katie Landgraf  
14105 W Fieldpoint Drive  
New Berlin WI 53151

September 5, 2007

Senate Health Committee  
Room 411 South  
State Capitol  
Madison WI

Dear Committee members:

I would hope that anyone who changes my meds for any reason would let me know and let my doctor know. I have a job and I work hard with my doctor so I can have the best seizure control possible.

It is very important to me to know that I can continue to take the medicines that work best for me.

Thank you,

Katie Landgraf

Laurie Landgraf  
14105 W Fieldpoint Drive  
New Berlin WI 53151

September 5, 2007

Senate Health Committee  
Room 411 South  
State Capitol  
Madison WI

Dear Committee members:

As a mother with an adult child who has epilepsy, I have hopes and dreams for my daughter, Katie. We also have the usual family worries, such as who will care for Katie when we no longer can. We've worked so hard over the years with specialists, to make sure that Katie can have the best seizure control and the best quality of life possible. One day this job may fall to a brother or a spouse.

Right now Katie takes three medications for her seizures, only one of which is available as a generic. Someday all three of her medications will be available as generics. When that time comes, we want Katie to be able to get the medicine that works for her. We want her to be a working, contributing member of society.

SB 71 will insure that Katie will get the medications that truly work for her, or that she and her physician will be notified anytime a substitute formulation is dispensed. This bill will relieve us of one worry that we have as a parent, as a care giver, or as a concerned citizen: that Katie will get the medications she needs and that she will be able to take generics safely. That's one less worry on our plate, and we will be grateful for your support of SB 71.

Sincerely,

Laurie Landgraf

Cynthia Piotrowski  
Executive Director  
Epilepsy Foundation Central & Northeast Wisconsin  
1004 First Street, Suite 5  
Stevens Point, WI 54481  
[cindypiotrowski@efcnw.com](mailto:cindypiotrowski@efcnw.com)  
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- We see health care trends in the problem calls we receive from clients
- Clients are calling when they get home and they don't recognize the medications that have been dispensed
- The Epilepsy Foundations in Wisconsin would like to enlist pharmacists as an important treatment partner and insure that before any kind of substitution is made at the point of sale the patient and their physician are in the loop
- The American Academy of Neurology and the American Epilepsy Society have charged their members with filing Food and Drug Administration Medwatch reports about adverse incidents. A recent poll indicates that only 13% of neurologists have done so, but this is because neurologists currently have no way of knowing when these substitutions are made
- SB 71 insures that physicians will be able to adjust doses, order blood levels, or monitor their patients as necessary when substitutions occur.
- EF clients want cheaper co-pays and they want medicines that are affordable – just like everyone else
- SB 71 insures that they can have confidence in generics and that their physicians will takes steps when their formulation changes due to inconsistency of supply

**Testimony from the Pharmacy Society of Wisconsin  
Before the State Senate Committee on Health and Human Services**

**Senate Bill 71**

**Tom Engels, Vice President of Public Affairs**

**Wednesday, September 5, 2007**



**PHARMACY  
SOCIETY OF  
WISCONSIN**

*"Leading Our Profession  
in a Changing  
Health Care Environment"*

The Pharmacy Society of Wisconsin opposes the passage of Senate Bill 71 because this legislation will not offer the protections to people with epilepsy that are implied by the bill. Pharmacists fully respect the right of people with epilepsy to obtain medications that offers them the best treatment. That exists today.

But the reality is, their treatment is not solely up to them. It is not up to pharmacists, it is not up to their physicians, it is up to the pharmacy benefit manager that is responsible for managing the prescription drug claims for their health insurer.

This legislation is similar to legislation that has been introduced in approximately 16 other states and has been financially supported by pharmaceutical manufacturers.

This legislation has been introduced at the request of the Epilepsy Foundation that would prohibit the substitution of prescription medications used for the treatment of epilepsy. This legislation is similar, but not identical, to a proposal that was introduced in the last Wisconsin legislative session. To date, no state has enacted this type of policy.

Under the provisions of this bill, a pharmacist would be prohibited from substituting an equivalent generic medication for its brand counterpart and from substituting a generic medication from one manufacturer for an equivalent generic medication made by another manufacturer, for all prescription products used in the treatment of epilepsy. A substitution would only be allowed with the consent and authorization of both the prescribing practitioner and the patient (or the patient's spouse, parent or legal guardian). Patients who have been diagnosed with epilepsy should have their condition carefully monitored and they should not have their treatment options inappropriately limited by insurance company policies.

**Generic Substitution in Wisconsin**

As it relates to interchange of prescription drug products, Wisconsin has taken a common and conservative approach that relies upon a sophisticated therapeutic equivalency testing process of the Food and Drug Administration (FDA). In Wisconsin, medications available for substitution only include those that meet the most rigorous equivalency tests and that receive the FDA's A/B rating.

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Wisconsin pharmacists work everyday to help patients in their medical treatments and help to reduce the cost of prescription medications by dispensing lower cost generic medications. In fact, Wisconsin law requires pharmacies to dispense a therapeutically equivalent generic prescription drug if it is lower in cost. This practice has been proven to help lower the cost of health care while maintaining the quality of treatment.

There are some instances where a prescribing practitioner will request that a specific medication be dispensed to a patient. In that case the prescribing practitioners will indicate that directive by writing "dispense as written" (DAW) on the prescription order. Most insurers and health plans provide a system for such a product to be considered for approval, dispensing and reimbursement.

### **Related Information**

In the co-sponsorship memo that was circulated to legislators there was a reference to injured Iraq war military personnel who suffered severe head injuries. Ironically, active duty military personnel can receive any prescription drug they are prescribed — the United States Department of Defense (DoD) doesn't have a prescription drug formulary (a selected list of drugs that can be dispensed). However, when a member of the armed services leaves active status he or she becomes eligible for medical care, including prescription drugs, from the Veterans Administration (VA). Although the VA pharmacy system does employ a prescription drug formulary, VA pharmacies are not subject to Wisconsin pharmacy laws and regulations, including the provisions of this bill, should it become law.

### **Unintended Consequences**

Some medications are prescribed for multiple symptoms, including epilepsy. The legislation would prohibit substitution of these medications if they are used in the treatment of epilepsy, but not if they are used for other conditions.

Patients receiving a generic epilepsy medication may find it difficult to receive treatment when the pharmacy provider selects an alternate generic manufacturer of the epilepsy product. It is common for a pharmacy or the pharmacy's wholesale distributor to change sources of generic products based upon the availability of the product and pricing advantages from one manufacturer over another. Changes in generic supply can change literally every month. It is possible that a patient would be unable to locate a pharmacy that stocks the very same generic manufacturer's product. Patients would also be set-up for failure as they are admitted or discharged from a hospital that may stock a different generic manufactured product than what the patient had received from a community pharmacy. Further, generic medications cost about 1/4 of the brand-name medication cost, on average, although the difference varies from medication to medication. If enacted, this legislation will result in higher health care costs — for epilepsy patients, businesses and insurers alike.

### **Proponents Raise Concerns with the Bioequivalence of Substituted Products**

The major concerns raised by proponents of this legislation are problems that may arise with the substitution of any medication used in the treatment of epilepsy. They argue that patients who have epilepsy should be allowed to maintain access to the same medication by the same manufacturer in order to minimize the potential of a seizure due to therapeutic differences between products. To illustrate this point, advocates reference the bioequivalence of generic medications not only from their brand name counter-parts but also from generic to generic.

The United States Food and Drug Administration states, "a generic drug is the same as a brand name drug in dosage, safety, strength, how it is taken, quality, performance and intended use. The FDA bases evaluations of substitutability or "therapeutic equivalence" of generic drugs by requiring and testing that the drug product contains identical amounts of the same active ingredient(s) as the brand name product. Drug products evaluated as "therapeutically equivalent" can be expected to have equal effect and no difference when substituted for the brand name product."

Bioequivalence of different versions of a drug can vary by up to 20% (80-120%), because for most drugs, such variation does not noticeably alter effectiveness or safety. However, actual differences between FDA-approved generic and trade-name drugs are generally much smaller than the allowable 20%. The FDA reports that actual differences are 3.5% on average and rarely exceed 10% in any single study of bioequivalence.

PSW recognizes that sometimes generic substitution is not appropriate. For example, some generic versions cannot be determined to be bioequivalent to the original drug because no standards for comparison have been established. These versions should not, and in Wisconsin may not, be interchanged for the original drug.

### **PSW Recommended Action**

While the intent of the proponents of this legislation is understandable, the negative consequences associated with its passage are clear. PSW recommends that the legislation be rejected. PSW further recommends that the Office of the Insurance Commissioner ensure that patients with epilepsy are not inappropriately denied access to necessary therapies by their insurer or health plan.

# Big Drug Makers Help Patient Groups Lobby; More Attention to States

By SARAH RUBENSTEIN 7/13/07

In state legislatures across the country, the Epilepsy Foundation has been campaigning for bills that would make it harder for pharmacists to switch patients to inexpensive generic epilepsy pills. The effort is getting behind-the-scenes support from drug companies—a sign of how the industry, long a potent lobbying force in Washington, is increasingly looking to states to achieve its goals.

The foundation, a nonprofit group supported by the drug industry, says switching to generics could cause dangerous seizures. The Food and Drug Administration says it hasn't seen persuasive evidence for that, and it believes each generic is equivalent to the brand-name drug it copies.

Four major brand-name drugs used for epilepsy are expected to lose patent protection and face generic competition between next year and 2010. Those four drugs generated \$5 billion in U.S. sales last year, according to IMS Health, meaning the state legislation could

## Top Treatments

U.S. sales of prescription drugs used to treat seizure disorders, in millions

2007 (Jan to April) 2006

Topamax \$656.6 \$1,825.4

Lamictal 638.9 1,684.3

Lyrica 306.8 727.8

Keppra 299.7 710.5

Depakote 257.1 770.4

Note: Sales figures include prescriptions for other uses such as migraine prevention (Topamax and Depakote), bipolar disorder (Lamictal and Depakote) and neuropathic pain (Lyrica)

Source: IMS Health

have a significant bottom-line impact. Some of the \$5 billion figure reflects sales of the drugs for other ailments.

Generic drugs are the centerpiece of efforts to tame growth in America's prescription-drug bill, which topped \$270 billion in 2006. When a doctor writes a prescription for a brand-name drug, pharmacists are usually permitted in most states to make an automatic switch to a generic judged equivalent by the FDA.

The epilepsy legislation would carve out an exception to that rule, with many of the bills requiring that doctors explicitly approve such a switch. Tennessee has passed a weaker version that requires doctor notification but not consent. Around 25 other states have considered some form of restriction in the past year.

It isn't the only health issue where states have been the central battle-

Please turn to page A10

Wall St. Journal



# Drug Industry Fights Switch to Generic Pills for Epilepsy

Continued from Page One

ground. Earlier this year, Merck & Co. drew fire for lobbying states to require that preteen girls receive its cervical-cancer vaccine to attend school. Merck stopped its direct lobbying in February, but a group of female state legislators who receive funding from the drug maker continue to push for the laws.

States often move faster than Congress, says Ian Paik, who runs state policy for the Pharmaceutical Research and Manufacturers of America, or PhRMA, the drug industry's trade group. State legislation can move "from idea, to passage, to governor's signature in 90 days, sometimes faster than that," she says. "So the action is in the states."

Campaign contributions to state candidates by pharmaceutical manufacturers and their employees rose to about \$8.8 million for 2006 from about \$4.6 million for 2005, according to the National Institute on Money in State Politics. Drug makers spent more than \$44 million on state lobbying in 2005 and 2006, the last years for which figures are available, according to the Center for Public Integrity.

In state legislatures, as in Congress, the drug industry often enlists nonprofit health and patient-advocacy groups to advance its agenda. In the epilepsy case, the Epilepsy Founda-

tion is in discussions of the drug-switching issue. Foundation leaders note that the state bills would generally require doctor permission for several kinds of switches, including when a patient goes from a generic to a brand.

"These are people's lives that we're talking about—nothing about stock options and stock value and how this would affect [companies'] bottom line. That would be insulting to us to have discussions like that," says Sindi Rosales, the head of a foundation affiliate in Texas, one of the states that weighed legislation this year. She says pharmaceutical companies are "fabulous partners" and their help in several areas "has been amazingly tremendous," but the companies leave it to the foundation to call the shots.

For their part, company executives describe their lobbying role as limited and say the bills were primarily an initiative of the foundation, although they acknowledge in certain cases that company officials have gotten directly involved. Executives say the aim of these activities is to protect the health of patients. "Our issue is not selfish to ward our individual product," says Richard Denness, a vice president at Belgium-based UCB. "It's a real concern in the minds of prescribers.... All it takes in the scheme of things are one or two patients to have a tragic event."

In the late 1990s, the national Epilepsy Foundation, based in Landover, Md., raised concerns about anecdotal reports that some patients experienced seizures and side effects after switching epilepsy drugs. Some of the episodes involved patients who had been switched to a generic from a branded drug. The foundation also worried about cases in which patients were switched from one generic version of a drug to another generic version of the same drug.




When the FDA approves generics, it requires manufacturers to show in human studies that their copycat pills deliver a similar amount of active ingredient to the bloodstream as the brand-name original. However, the agency doesn't require exact equivalence. That would be an impossible bar to clear, because there is always a slight variation in the way people absorb drugs.

The foundation theorized that some generic pills had a meaningful difference from the brands. This difference, it posited, meant patients were getting more or less of the drug in their blood, causing some of them to have seizures or side effects. Foundation officials floated the idea in a 1999 meeting with the FDA.

The FDA's response: "Show us the data," recalls Sandy Pinucane, who oversees state and federal policy for the foundation. The agency, unpersuaded by what it saw, stood firm in its long-held position that the difference

## Drug Dollars

Epilepsy Foundation contribution ranges for some drug companies:

	\$500,000 - \$999,999 Eli Lilly GlaxoSmithKline UCB
	\$100,000 - \$499,999 Abbott Laboratories Novartis Pharmaceuticals Ortho-McNeil Neurologics Pfizer
	\$25,000 - \$49,999 PhRMA (trade group)

\*Subsidiary of Johnson & Johnson  
Source: Epilepsy Foundation

were too small to have a tangible impact on patients.

Coning up with the kind of evidence the FDA sought would have required a major clinical trial to demonstrate that the seizures were a direct result of the switches, Ms. Pinucane says. The foundation thought it would be difficult to enroll patients for such a trial, and the costs were prohibitive, she says. For years the foundation didn't push the matter, beyond developing policy statements and encouraging patients and doctors to report problems to the FDA.

In early 2006, the issue re-emerged as legislation requiring doctor permission for switches was proposed in Illinois. That's the home state of Abbott Laboratories, which makes Depakote, a leading epilepsy pill that is expected to face generic competition next year. The bill passed, but in watered-down form. An Epilepsy Foundation official in Illinois says Abbott helped (and lobbying for stronger provisions that were considered this year but didn't pass. Abbott said it supports some foundation initiatives but declined to give specifics.

In May 2006, the national Epilepsy Foundation convened a committee of medical experts to examine the question. The committee found a lack of authoritative studies showing that such drug switches cause problems, says its chairman, Steven Schachter, a Harvard Medical School neurologist. Nonetheless, it recommended that doctors give explicit approval for switches, citing anecdotal reports of seizures and noting that such attacks can be serious.

Last fall, the American Academy of Neurology issued a statement making a similar recommendation. The academy says it receives funding from drug makers for educational programs but not for developing medical guidelines.

At a meeting last September, the national foundation told its local affil-

ates that if they wanted to push for legislation regulating switches, the foundation would provide model legislation and support, Ms. Pinucane says. It also told them to "maintain independence from any company that's going to be interested in this issue," she adds. The 50-plus affiliates operate largely autonomously.

The sponsor of a bill in Georgia, state Rep. Charlice Byrd, says a UCB official was the first person to raise the epilepsy-drug switching issue with her. The Belgian company makes the epilepsy drug Keppra. Ms. Byrd says she was sympathetic because her late mother had epilepsy.

Charlotte Thompson, who joined the foundation's Georgia affiliate as executive director last September, says she became aware of the bill after hearing about it from UCB. "When we realized [Rep. Byrd] was introducing this and looked at it and studied what it was, then we jumped on the bandwagon," Ms. Thompson says. Six lobbyists for three companies joined a committee created by the Epilepsy Foundation to work on the legislative process, she says.

Ms. Byrd says several pharmaceutical-company lobbyists offered their support. Abbott lobbyist Guy Mosier "was extremely helpful working with legislators to help them understand the importance and that this piece of legislation was strictly for patient protection," Ms. Byrd says. Mr. Mosier declined to comment.

Ms. Byrd introduced the bill in the Georgia House in January of this year. At a Feb. 7 hearing of the House's health committee, Lisa Joiner, executive director of the Georgia Psychiatric Physicians Association, testified in support. Ms. Joiner was at the time also a Glaxo lobbyist, which she didn't mention at the hearing. In an interview, she said she didn't raise her tie to Glaxo because the company hadn't asked her to lobby for the bill.

Two days later, epilepsy patients and parents of patients visited lawmakers' offices to ask them to support the bill. The Epilepsy Foundation's Ms. Thompson says drug-company lobbyists accompanied the visitors.

Kimberly Oviedo says her 6-year-old daughter had seizures last year after being switched to a generic version of the epilepsy drug Zonegran. She says she supported the bill because she wouldn't "want any other person to have to go through what we've been through with our kids." Ms. Oviedo also has a son who suffers from epilepsy.

The bill passed the Georgia House in a 161-0 vote on Feb. 28, but it stalled in the Senate after groups representing pharmacists and generic-drug makers mounted heftier opposition to it in that chamber. Pharmacies often earn bigger profit margins on generics than

on branded drugs.

Ms. Thompson says the foundation plans to meet with the Georgia Senate leadership this summer to try to gather its support for next year.

In Texas, two local Epilepsy Foundation affiliates decided to approach at Abbott official after they resolved to push for a bill, says Ms. Rosales, the head of one of the affiliates. Abbott and other drug makers helped fund the foundation's Texas lobbying, she says.

Ms. Rosales, whose daughter used to have seizures, says she felt deeply about the bill but worried about being perceived as a "mouthpiece for the pharmaceutical industry." She nonetheless hired Santos Alliance, a firm that also represents PhRMA, as her affiliate's lobbyist. Ms. Rosales says it's difficult to find a health-care lobbyist with no drug-maker clients. Frank Santos, head of the lobbying firm, says PhRMA was "absolutely 100% not involved" with the bill.

At a March hearing in the Texas Senate, Ron Hartmann, a lobbyist for generic-drug maker owned by Novartis AG of Switzerland, testified against the bill. He said he suspected the bill was "less focused on the citizens of Texas than on protecting the market share of a few brand-name drugs that are scheduled to go off-patent in the next few years."

State Sen. Kyle Janek, the bill's sponsor, responded that Mr. Hartmann had "impugned my motivations," and added that, if Mr. Hartmann would "abstain from doing that," then he would abstain from calling Mr. Hartmann a "high-priced shill." Mr. Hartmann apologized. In 2006, Sen. Janek received about \$19,000 in campaign contributions from drug makers. He says he sponsored the bill because it was in the best interests of patients.

The bill passed the state Senate in April, but failed to come up to a vote in the House after debate in that chamber's health committee. Three of the committee's members said in interviews later that they were skeptical of the bill because they thought it was being pushed by drug companies. Generic-drug makers and pharmacists lobbied heavily against the bill.

Meanwhile, some doctors are pushing harder for a study that would settle the matter. Michel Berg, a neurologist who is chairman of an American Epilepsy Society task force examining the switching issue, has opened discussions with the FDA about what kind of trial would be necessary.

For now, Gary Buehler, the director of the FDA's office of generic drugs, says the agency is skeptical that the drug switches cause seizures. "The only way you can somehow pin this down is to do a good study," says Mr. Buehler.

## Generic Debate

The situation: The Epilepsy Foundation, helped by drug makers, is backing state bills that would make it harder for pharmacists to switch patients to generic epilepsy pills.

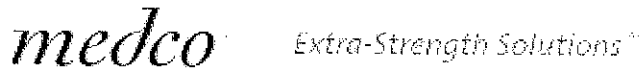
The background: The foundation says switches made by doctors are safe. It says it is a "real concern" in the minds of prescribers. All it takes in the scheme of things are one or two patients to have a tragic event.

tion's state affiliates, rather than the companies, are taking the most prominent part in the lobbying.

The foundation and its state affiliates receive funding from the epilepsy-drug makers. GlaxoSmithKline PLC and UCB SA donated \$500,000 to \$999,999 each in fiscal 2006 to the national foundation, according to its annual report. Abbott Laboratories and a Johnson & Johnson unit each contributed \$100,000 to \$499,999. Representatives of four drug companies sit on the foundation's board, as does PhRMA chief Billy Tauzin.

The foundation and its affiliates had about \$77 million in revenue in 2005, about \$48 million of which came from state and federal grants.

The foundation says its diverse funding base shields it from undue drug-company influence, and the industry executives on its board don't partici-



**To:** Committee on Health & Human Services

**From:** Jason Johns

**Re:** Medco Health Solutions Opposition to SB 71

**Date:** September 5, 2007

**Senators;**

Medco Health Solutions, Inc., the world's largest pharmaceutical benefits manager with almost 60,000 retail pharmacies in our network, respectfully opposes SB 71.

By requiring both physician and patient consent before dispensing a generic product for any treatment of epilepsy or convulsions, this legislation will make it harder for patients to access affordable care. At the same time, by preventing Employers or Health Plan Sponsors from designating different co-pay amounts for specific drugs, this bill will also inhibit competition, encourage plans to shift a greater share of the cost to the patient, and/or reduce the plan's ability to maintain meaningful coverage of prescription drugs.

**AB 150 Will Make it Harder for Patients to Obtain Lower Cost Therapies for Seizures**

- This issue stems from concerns in the past when manufacturers couldn't produce reliable generic versions of this type of medication.
- Now, and for the past ten years however, many generic seizure drugs have come on the market and have been given an "A" rating by the FDA., meaning they are interchangeable with the brand
- Requiring consent from prescribers and patients before dispensing a generic medication creates an administrative burden that would deter patients from using lower-cost therapies that would have the same efficacy as their brand name counterparts.
- This group of medications is known for having a narrow therapeutic index, because a small variation in the dosage or concentration of these drugs can be important.

**The Solution Lies with the Pharmacist, Not the Legislature**

- Because a change from a brand medication to a brand medication made by a different manufacturer can make a huge therapeutic difference for patients just as easily as a change from a generic to a different generic can, pharmacists should be

telling patients and physicians when they make a change in the medications they dispense.

- Notifying the patient of medication changes should be a responsibility of the pharmacist and should be an issue of professional practice, not legislation.

**Employers struggle with health care costs, yet AB 150 prohibits the use of cost-management tools.**

- Payors as part of their plan design, create formularies or drug lists that indicate which drugs (both brand and generic) they will cover. They incentivize generics as lower cost options A-rated generics are available to be listed on the formularies they create.
- In the instance when a generic medication has been tried by the patient and is unsuccessful, payors should have an exceptions process to allow for lower cost brand medications.
- In a time of rapidly escalating drug costs, policymakers should be focused on encouraging the use of innovative and effective cost control techniques rather than discouraging them.
- The bill would also prohibit plans from implementing formulary management programs that promote generics and lower cost branded drugs. The FTC determined that PBMs use formulary management programs to drive price competition among manufacturers.

Based on the reasons above, we think you will agree that SB 70 will only harm the patients receiving these types of prescriptions, not help them. We ask that you oppose SB 70.

Thank you,

Jason E Johns, Esq.

Tenuta & Johns

On Behalf of Medco Health Solutions, Inc.

Warren La Duke  
210 S. Academy St  
Stoughton, WI 53589

September 5, 2007

I have had epilepsy my entire life and am here to share my experience with generic medications that were substituted to me through my regular prescription for seizure control without my knowledge or consent.

In January 2006, while taking Keppra and Zonigran my seizures were well controlled. Beginning with my February monthly refills, and continuing for four months, the Zonigran prescription was substituted with a generic version unbeknown to me. Within a week of taking these generic prescription there was a noticeable change in my seizure activities.

Ultimately this change resulted in my having complex partial seizures again, and I had to voluntarily hand in my driver's license until my seizures were once again under control. As a result of appointments with my neurologist and an understanding pharmacist willing to work with me I was able to get back on the medication that was prescribed and get my seizures under control once again.

I consider myself one of the lucky ones because of the excellent health benefits provided to me through my work. I'm able to get some extra time off to make the necessary appointments to see my doctor when the time is available, to get the brand name medications, and find ways to get around the temporary limitations created when I lost my drivers license.

Unfortunately, many people who have epilepsy as a pre-existing condition often struggle with their health coverage and are provided the cooperation from their work. Because of cost, or their health coverage, they end up taking the generic brands. When pharmacies switch the generic brands from manufactures so often, as they did with myself, problems similar to mine will continue and a person may never get their seizures under control just because of the constant change. It's almost like taking a new medication with every switch in manufacture brand.

Therapy failure for epilepsy means either a breakthrough seizure if your blood level gets low or toxicity if it goes too high. With generics the difference is enough to make such a difference. By informing both the patient and the prescribing physician, we can help avoid any unnecessary therapy failure, unnecessary expense and difficulty maintaining health at work or school.



Jim Doyle, Governor  
John A. Scocos, Secretary

**STATE OF WISCONSIN, DEPARTMENT OF VETERANS AFFAIRS**

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September 5, 2007

Senator Jon Erpenbach, Chair  
Committee on Health and Human Services  
Wisconsin State Senate  
State Capitol Room 8 South  
Madison, WI 53707-7882

Dear Chairman Erpenbach and Committee Members:

On behalf of the Wisconsin Department of Veterans Affairs and the state's nearly half-million veterans we serve, thank you for today's hearing on 2007 Senate Bill 71, regarding epilepsy drugs.

Post-traumatic epilepsy has been repeatedly linked to traumatic brain injury (TBI), perhaps the signature injury of the ongoing wars in Iraq and Afghanistan.

The Wisconsin Department of Veterans Affairs is in support of SB 71 (LRB 1893/1) and its Assembly companion, AB 150 (LRB 1513/2), introduced by Rep. Terry Musser. A letter in support of this legislation is attached.

Please feel free to contact us with any questions you may have.

Sincerely,  
DEPARTMENT OF VETERANS AFFAIRS

A handwritten signature in dark ink, appearing to read "William J. Kloster". The signature is fluid and cursive, with a large, stylized "W" and "K".

WILLIAM J. KLOSTER  
Acting Secretary

Cc: Rep. Terry Musser



**STATE OF WISCONSIN, DEPARTMENT OF VETERANS AFFAIRS**

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Jim Doyle, Governor  
John A. Scocos, Secretary

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February 8, 2007

Dear Legislators:

I am writing in support of LRB 1513/2, a bill that proposes to prohibit the substitution of anti-seizure medications with generic equivalents without the approval of the patient and prescribing physician. While current law permits some substitutions by a pharmacist for medications as prescribed, anti-seizure medications often require very careful consideration to meet a very narrow therapeutic range of treatment for patients suffering from seizures – seizures often caused by brain injuries sustained by military service members in a combat zone.

Our armed forces are sustaining attacks by rocket-propelled grenades, improvised explosive devices, and land mines almost daily in Iraq and Afghanistan. Many service members have sustained traumatic brain injury as the result of these attacks. The Defense and Veterans Brain Injury Center (DVBIC) at Walter Reed Army Medical Center recently screened Iraq war veterans who suffered from the effects of a bomb blast. They noted that 61% of all service members injured by bomb blasts also sustained brain injuries, and that brain injuries are the leading cause of epilepsy.

It is important to note that a single breakthrough seizure not only puts a veteran at great physical risk, it also places him or her in financial jeopardy. In Wisconsin, as in many states, a person who experiences a seizure automatically loses his/her drivers license until they can demonstrate that they have been seizure-free for 90 days. As you would expect, this is very disruptive to the veteran, the veteran's employer, and his/her family.

We share the interest of the Epilepsy Foundation and the American Academy of Neurology in preventing the substitution of anti-seizure medications without the approval of the patient and prescribing physician. It is my understanding that Illinois passed a similar law, and that the measure has recently been introduced in twenty other states.

For more information on brain injuries sustained by war veterans, please visit the Defense and Veterans Brain Injury Center's website: [www.dvbic.org](http://www.dvbic.org).

Thank you for your consideration.

Sincerely,  
DEPARTMENT OF VETERANS AFFAIRS

A handwritten signature in black ink, reading "John A. Scocos", is positioned above the printed name and title.

JOHN A. SCOCOS  
Secretary